

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings of claims in the application:

LISTING OF CLAIMS:

1. (currently amended) A pharmaceutical extended release composition in the form of a pressurized aerosol or non-pressurized aerosol, constituting a spray suspension comprising:

at least one liquid excipient [[and]] being one of:

(i) a mixture of water and a pressured aerosol propellant selected from the group consisting of from dimethylether, butane, propane, mixtures of butane and propane, fluorinated hydro carbons, nitrogen, carbon dioxide, nitrous oxide, and combinations thereof, wherein the composition is in the form a pressurized aerosol, and

(ii) water or a mixture of water and an organic solvent, wherein the composition is in the form a non-pressurized aerosol;

at least one solid excipient which essentially is insoluble in the liquid excipient~~[[,]]~~; and

at least one pharmaceutical active ingredient, wherein the solid excipient after actuation of the spray suspension forms a matrix into which the pharmaceutical active ingredient is incorporated so as to form a porous suspension.

2. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 1, ~~characterised in that~~ wherein the composition is in the form a pressurized aerosol, and the liquid excipient is a mixture of water and a pressured aerosol propellant, such as dimethylether, butane, propane, mixtures of butane and propane, fluorinated hydrocarbons, nitrogen, carbon dioxide and nitrous oxide.

3. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 2, ~~characterised in that also~~ wherein water is ~~included in the composition, preferably present~~ in a concentration between 10-95w/w %, ~~and more preferably in a concentration between 30-95 %.~~

4. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 1, ~~characterised in that~~ wherein the composition is in the form a non-pressurized aerosol, and the liquid excipient is water or a mixture of water and an organic solvent, such as alcohols.

5. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 1, ~~characterised in that~~ wherein the solid ~~excipient~~ excipient consists of inorganic salts or polymers selected from the group consisting of natural polymers, modified natural polymers, synthetic polymers and mixtures thereof.

6. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 5, ~~characterised in that~~ wherein the polymeric material consist of natural polymers selected from the group consisting of native cellulose, ~~such as Cellulose I.~~

7. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 6, ~~characterised in that~~ wherein the native cellulose is micro crystalline cellulose or milled ~~qualities of~~ micro crystalline cellulose.

8. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 1, ~~characterised in that~~ wherein the excipient particles are suspended in the liquid excipient, wherein the active ingredient is either dissolved, partly dissolved or suspended in the liquid or precipitated on the surface of the solid excipient and where the excipient particles after actuation can form a matrix, in-situ, on the administration site, ~~such as the skin.~~

9. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 8, ~~characterised in that the composition also contains~~ further comprising at least one additional solid excipient which is capable of retarding the drug release from the matrix formed in-situ.

10. (currently amended) [[A]] The pharmaceutical

composition in accordance with claim 8, ~~characterised in that~~ wherein at least 50% by weight of the excipient particles have a particle size not less than 0.1µm and where at least 90% by weight of the excipient particles have a particle size less than 50 [[go]] µm.

11. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 1, ~~characterised in that~~ wherein the excipient particles together with the active ingredient forms a plurality of larger individual suspension particles ~~(suspension particles)~~.

12. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 11, ~~characterised in that~~ wherein the excipient particles together with the active ingredient ~~forms~~ form a plurality of larger individual particles that are porous and that the composition ~~also contains~~ further comprises at least one additional solid excipient which is capable of retarding the drug release from the suspension particles.

13. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 9, ~~characterised in that~~ wherein the additional solid excipient is a polymer, with pronounced ductile properties thereby capable of reducing the porosity and/or average pore diameter of the suspension particles, or the matrix formed in-situ.

14. (withdrawn-currently amended) [[A]] The pharmaceutical composition in accordance with claim 11, ~~characterised in that~~ wherein the composition also contains at least one additional solid excipient which is capable of forming an outer membrane layer around the suspension particles, where the membrane layer retards the drug release and where the membrane layer is composed of non-polymeric-or polymeric materials such as calcium phosphate, ethyl cellulose, methacrylate copolymer, polyamide, polyethylene, polyvinyl alcohol or polyvinyl acetate.

15. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 11, ~~characterised in that~~ wherein at least 50% by weight of the suspension particles have a particle size not less than 10 um and where at least 90% by weight have a particle size smaller than 150µm ~~150) J. m.~~

16. (currently amended) [[A]] The pharmaceutical composition in accordance with claim 11, ~~characterised in that~~ wherein the suspension particles have an essentially isodiametrical shape[[,]] and ~~preferably the particles also have a~~ smooth surface texture.

17. (currently amended) A method of preparing porous suspension particles comprising an active ingredient, in accordance with claim 11, ~~characterised in that it~~

~~comprises~~ comprising the steps of ~~[[;]]~~:

a. wet-milling or dry-milling the solid excipient (s) or a mixture of at least one active ingredient and a solid excipient(s) in a milling equipment inducing essentially compression and shear forces, resulting in fine particulate quality, where more than 90 % by weight is smaller than 5µm ~~5µm~~ and ~~preferably smaller than 2 µm~~; and

b. drying and aggregating the product of step a. or the product of step a. with the addition of at least one active ingredient, in fine particulate form, ~~by e. g. spray drying or any other drying procedure possible, which will to~~ produce essentially isodiametrical aggregate particles.

18. (currently amended) A method of preparing porous suspension particles comprising an active ingredient, ~~,, c h a r a c t e r i s e d i n t h a t i t c o m p r i s e s t h e s t e p s o f ;~~ comprising the steps of:

a. preparing porous excipient particles, excluding any active ingredient, ~~are prepared~~ in accordance with the method described in claim 17; and

b. adding at least one active ingredient ~~is added~~ to the product of step a. whereby the active ingredient is essentially positioned within the pore structure of the product of step a.

19. (withdrawn) A method of preparing non-porous suspension particles (including an active ingredient), in

accordance with claim 14,

*c h a r a c t e r i s e d* in that the active ingredient is applied, by e. g. a coating process, as an outer layer on solid, non- porous, excipient particles.

20. (withdrawn) A method of applying a drug release retarding outer membrane layer to the suspension particles, prepared in accordance with the method described in claim 17, and where the membrane layer is composed of non-polymeric-or polymeric materials such as calcium phosphate, ethyl cellulose, methacrylate copolymer, polyamide, polyethylene, polyvinyl alcohol or polyvinyl acetate.

21. (previously presented) Suspension particles obtainable by a method according to claim 17.

22. (currently amended) A pharmaceutical preparation, ~~utilising~~ comprising the composition in accordance with claim 1, ~~c h a r a c t e r i s e d~~ in that wherein the preparation is a cutaneous spray, an ear spray or a nasal spray.

23. (currently amended) [[A]] The pharmaceutical preparation, ~~utilising the composition or the suspension particles in accordance with claim 22, c h a r a c t e r i s e d~~ in that according to claim 22, wherein the preparation ~~contains~~ comprises as the active substance, morphine, morphine sulphate, morphine hydrochloride, ketoprofen, lidocaine hydrochloride or other

substances effective in the treatment of pain or capable of inducing anesthetic effect.

24. (currently amended) [[A]] The pharmaceutical preparation, ~~utilising the composition in accordance with claim 22, characterised in that~~ according to claim 22, wherein the preparation is in the form of a ~~pressurised~~ pressurized aerosol or mechanical pump device.

25. (currently amended) A method for treatment of disorders, ~~wherein comprising administering~~ to an individual afflicted with a disorder is administered an effective amount of a pharmaceutical composition, constituting a spray suspension comprising at least one liquid excipient and one solid excipient which essentially is insoluble in the liquid excipient and at least one pharmaceutical active ingredient.

26. (currently amended) [[A]] The method for treatment of disorders according to claim 25 wherein the drug release rate is controlled by varying the area of said composition covering the skin of an individual.

27. (currently amended) [[A]] The method for treatment of disorders according to claim 26 wherein the drug release rate is controlled by using a device with a range of increasingly sized openings or a device with a diaphragm where the opening diameter can be varied.



28. (currently amended) [[A]] The method for treatment of disorders according to claim 25 wherein the drug release duration is controlled by varying the height of said composition covering the skin of an individual.

29. (currently amended) [[A]] The method for treatment of disorders according to claim 28 wherein the drug release duration is controlled by using a specific spraying time.

30. (currently amended) [[A]] The method for treatment of disorders according to claim 25 wherein the drug release rate is controlled by varying the area of said composition covering the skin of an individual, and wherein the drug release duration is controlled by varying the height of said composition covering the skin of an individual.

31. (currently amended) [[A]] The method for treatment of disorders according to claim 30 wherein the drug release rate is controlled by using a device with a range of increasingly sized openings or a device with a diaphragm where the opening diameter can be varied.

32. (currently amended) [[A]] The method for treatment of disorders according to claim 30 wherein the drug release duration is controlled by using a specific spraying time.